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Section 5

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date 04-10-08 [21 CFR 807.92(a)(1)].

A. Contact Information [21 CFR 807.92(a)(1)]

Quantel USA

OCT 2 9 2009

601 Haggerty Lane

Bozeman, MT 59715

Tel: 406-586-0131

Fax: 406-586-2924

Contact person: Michael Johnson M.D.

B. Device Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: EXELO$_2$ Scanned CO2 Laser System for Dermatology

Device Common Name: CO2 Laser

Classification Name: Laser Instrument, Surgical Powered (per 21 CFR 878.4810)

Product Code: ONG

Panel: Dermatology and Plastic Surgery

Device Classification: Class II

C. Predicate Devices [21 CFR 807.92(a)(3)]

The EXELO$_2$ device uses similar technology and has equivalent physical output characteristics as the following predicate devices:

k080915 Reliant Fraxel re:pair Carbon Dioxide Laser

D. Device Description [21 CFR 807.92(a)(4)]

The $EXELO_2$ is a CO_2 laser device designed for dermatological use. It produces a coherent monochromatic radiation at the wavelength of 1.6 microns. The system is composed of a base which encloses the power supply and control interface, an articulated mirror arm, and a scanner handpiece.

E. Device Specifications [21 CFR 807.92(a)(6)]

The $EXELO_2$ outputs a monochromatic laser beam of 1.6 micron wavelength with selectable pulse durations of between 2 and 8 milliseconds. The laser power is adjustable in the range of 1-30 Watts. The spot size is 250 microns. The aiming beam has a wavelength of 635 nanometers and a power of less than 1 miliWatt. The scanner covers areas adjustable between 1 and 4 centimeters^2 and has a spot pitch of 0.25 to 3.50 millimeters.

F. Indications for Use [21 CFR 807.92(a)(5)]

The EXELO2 with the fractional scanning unit is indicated for ablative skin resurfacing in people with skin types 1, 2 or 3 based on Fitzpatrick skin type scale.

G. Performance Data [21 CFR 807.92(b)(2)]

The EXELO2 was tested on a series of 5 human subjects. Energy settings of 50mJ and 100mJ were used and punch biopsies were taken at 10 minutes, 3 days, 14 days, 21 days, and 28 days. Quantitative histology demonstrated substantial equivalence.

H. Conclusion [21 CFR 807.92(b)(3)]

Technologically, the $EXELO_2$ was found to be substantially equivalent to the currently cleared k080915 Reliant Fraxel re:pair Carbon Dioxide Laser. The indications for use are similar to these previously cleared devices. The risks and benefits for the $EXELO_2$ are argued to be comparable to the predicate devices. We believe that there are no new questions of safety or efficacy raised by the introduction of the $EXELO_2$.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 29 2009

Quantel Derma GmbH
% Quantel, USA
Mr. Michael Johnson
Medical Product Manager
601 Haggerty Lane
Bozeman, Montana 59715

Re: K090639
Trade/Device Name: EXELO² Scanned CO² Laser System for Dermatology
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONG
Dated: October 23, 2009
Received: October 27, 2009

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

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Indications for Use

510(k) Number (if known): k090639

Device Name: $EXELO_2$

Indications for Use:

The EXELO2 with the fractional scanning unit is indicated for ablative skin resurfacing in people with skin types 1, 2 or 3 based on Fitzpatrick skin type scale.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090639